

determination to be considered in the appeal.

**§ 423.2128 Action of the MAC.**

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in § 423.2122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to the enrollee at his or her last known address, to CMS, to the IRE, and to the Part D plan sponsor.

**§ 423.2130 Effect of the MAC's decision.**

The MAC's decision is final and binding unless a Federal District Court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 423.1980. An enrollee may file an action in a Federal District Court within 60 calendar days after the date the enrollee receives written notice of the MAC's decision.

**§ 423.2134 Extension of time to file action in Federal District Court.**

(a) An enrollee may request that the time for filing an action in a Federal District Court be extended.

(b) The request must:

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the enrollee shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in §§ 405.942(b)(2) or (b)(3) of this chapter.

**§ 423.2136 Judicial review.**

(a) *General rule.* To the extent authorized by sections 1876(c)(5)(B) and 1860D-4(h) of the Act and consistent with § 423.1976, an enrollee may obtain a court review of a MAC decision if the amount in controversy meets the threshold requirement estimated annually by the Secretary.

(b) *Court in which to file civil action.*

(1) Consistent with § 423.1976(c), any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

(2) If the enrollee does not reside within any judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 423.2130 or § 423.2134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 423.1990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff enrollee will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.